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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,327	02/24/2004	Paul J. Sheskey	63633	9686

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Intellectual Property Section
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,327	SHESKEY ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7, 11-15, and 19-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 11-15, and 19-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid particles.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') in view of Hardie-Muncy et al. (see below for citation) Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claim requires the same proportion of surfactant as well as the presence of drug in the fluid or solid used in the process as claim 1-2 in patent '828. Both the instant application and patent '828 teach a method of contacting particles with foam produced by combining a fluid with gas. In addition, the instant claim requires a range of molecular weights for the surfactant used as well as a range of particle sizes to be coated that each overlap with claims 1-2 of patent '828. However, patent '828 does not teach that the properties of the foam or its quantity relative to the particles.

Hardie-Muncy et al. teach the application of a coating to moisture sensitive particulate materials by foaming the coating medium then applying the foam to the particles (see abstract). They go on to teach that the foam has an overrun of 350% to 750% (see column 2 lines 44-51; instant claims 1-2). Although the reference is silent regarding the conditions under which the overrun is measured, it would have been most reasonable to make this measurement at ambient conditions (25°C and atmospheric pressure). Hardie-Muncy et al. go on to teach that the ratio of foam to particles is 1:0.05 to 1:20 (see column 2 lines 59-68; instant claims 1-2). Further, Hardie-Muncy et al. teach that this process results in the agglomeration of the coated particles into larger particles (see column 1 lines 56-57 and 63-column 2 line 3). Since it was known to coat and agglomerate particles with a foam, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the foam details and proportions as taught by Hardie-Muncy et al. in the process taught by patent '828'. Therefore claim 1 is obvious over claims 1-2 of U.S. Patent No. 7,070,828 in view of Hardie-Muncy et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-7, 11-12, 14-15, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (previously cited) in view of McTeigue et al. (previously cited), Lopez (previously cited), and as evidenced by USP Dictionary of U.S. Adopted Names and International Drug Names (previously cited), the Merck Index (previously cited), and Hardie-Muncy et al. (US Patent No. 4,476,145).

Parikh et al. teach the coating of drug containing particles cores that are 80 to 300 micrometers in size (see paragraph 34; instant claims 1-2 and 19-20). Parikh et al. go on to teach both a taste masking and texture masking coating that are utilized in the invention (see paragraphs 20-21 and 35). The taste masking coating is taught to optionally contain surfactants that are present at 2 to 10wt % and where glycerol monostearate and polysorbates are specifically envisioned (see paragraphs 41; instant claims 3-4 and 11-12). This coating is also taught to cover the entire surface of the core (see paragraphs 32 and 35). Parikh et al. go on to teach the solvents used to apply the coating, specifically naming water, methanol, acetone, ethanol, and isopropanol used separately or in mixtures (see paragraph 43; instant claims 1-2). The resulting particles are a granular material. After production of these coated particles, Parikh et al. teach the production of larger granules (agglomeration) by wet granulation as well as their subsequent drying (see paragraph 56; instant claims 1-2). Although Parikh et al. teach that several methods can be used to coat the particle cores, they do not teach coating by application of a foam (see paragraphs 43 and 52). Parikh et al. also do not teach a particular taste masking coating formulation where the proportion of components in the coating other than the surfactant and diluent (solvent) is limited to 25 wt%.

McTeigue et al. teach a method of producing a taste-masked pharmaceutical particle (see abstract). In particular, McTeigue et al. teach the importance of producing a continuous coating over the core of their particles to insure that no active ingredient is exposed (see paragraph 24 lines 1-4). McTeigue et al. go on to teach a listing of suitable surfactants to be included in the coating (see 20 lines 1-2 and 7-10). A particular example of the invention comprises a coating solution with 10% coating materials (e.g. materials other than diluent) which include cellulose acetate, hydroxypropyl methylcellulose phthalate, and polysorbate 80 (polymer/surfactant), where the polysorbate 80 constitutes 0.44% of the final solution (as calculated by the examiner) of the liquid diluent and surfactant portion (see example 2; instant claims 1-2, 6, and 14). The coating solution also uses a blend of acetone and water as the solvent (see example 2). The USP Dictionary of U.S. Adopted Names and International Drug Names (USAN) teaches that polysorbate 80 is a surfactant used in pharmaceuticals and, based upon its chemical structure shown by the Merck Index, has a molecular weight of 1344 (instant claims 1-3).

Lopez teaches a process of coating pharmaceutical solid forms (see column 1 lines 6-8). Lopez teaches that the process of coating solid forms by conventional means of dipping, pouring, or spraying often leads to unevenness in the coating layer (see column 1 lines 11-12 and 15-20). In addition, Lopez teaches that spray coating a liquid typically requires high pressures to appropriately atomize the coating medium and poses several challenges to uniform coating (see column 1 lines 46-75). The process taught by Lopez to circumvent the challenges of standard spray coating is amenable to

nearly any type of coating medium and results in even and uniform coating, as well as shortened processing times (see column 2 lines 65-66 and 73-75). Lopez teaches the method of introducing air into a coating composition, which contains a surfactant and water, to produce foam that is then sprayed onto the pharmaceutical solid (see example and column 3 line 72-column 4 line 9; instant claims 1-2). Lopez et al. also teach that the foam is broken when the particles are mixed into the foamed coating (see column 2 lines 32-38; instant claims 1-2).

Hardie-Muncy et al. teach the application of a coating to moisture sensitive particulate materials by foaming the coating medium then applying the foam to the particles (see abstract). They go on to teach that the foam has an overrun of 350% to 750% (see column 2 lines 44-51; instant claims 1-2). Although the reference is silent regarding the conditions under which the overrun is measured, it would have been most reasonable to make this measurement at ambient conditions (25ºC and atmospheric pressure). Hardie-Muncy et al. go on to teach that the ratio of foam to particles is 1:0.05 to 1:20 (see column 2 lines 59-68; instant claims 1-2). Further, Hardie-Muncy et al. teach that this process results in the agglomeration of the coated particles into larger particles (see column 1 lines 56-57 and 63-column 2 line 3).

Since Parikh et al. and McTeigue et al. both teach a taste masking coating on particles, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the particular proportions of components taught by McTeigue et al. for the taste masking coating in Parikh et al. In view of the teachings of Parikh et al. it would have also been obvious to one of ordinary skill in the art at the time of the

invention to use the taught water or a monofunctional alcohol, instead of the acetone/water blend in McTeigue et al. since they are taught to be functional equivalents (see instant claims 7 and 15). The complete coverage of the drug particles is needed to produce a completely taste-masked result, thus one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the invention of Parikh et al. in view of McTeigue et al. by using the foam coating technique of Lopez to help ensure that complete and uniform coverage of the particles could be achieved. Based upon the recitation of instant claim 1, dispersion of surfactant and foam components into the particles and agglomeration of the particles is a result of the step of contacting the foam with the solid particles; therefore this limitation is met by the foam coating method of Lopez. In addition Hardie-Muncy et al. teach that this contacting of particles with a foam results in a agglomeration of the particles, further supporting the connection of the "contacting" step with the agglomerated end product. Hardie-Muncy et al. also teach foam characteristics along with their method of coating moisture sensitive particles with a foam composition. Since many of the drugs taught by Parikh et al. were known to be moisture sensitive and the coating of particles with a foamed composition was known at the time of the invention, the use of the foam characteristics as detailed by Hardie-Muncy et al. would have been an obvious addition to the foam coating method taught by Parikh et al. in view of McTeigue et al. and Lopez. Therefore claims 1-4, 6-7, 11-12, 14-15, and 19-20 are obvious over Parikh et al. in view of McTeigue et al., Lopez, and Hardie-Muncy et al. and as evidenced by the Merck Index and the USP Dictionary of U.S. Adopted Names and International Drug Names.

Claims 1, 5, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. in view of McTeigue et al., Lopez, and Hardie-Muncy et al. and as evidenced by the Merck Index and the USP Dictionary of U.S. Adopted Names and International Drug Names as applied to claims 1-4, 6-7, 11-12, 14-15, and 19-20 above, and further in view of Edgren et al. (previously cited).

The modified Parikh et al. reference teaches both a taste masking and texture masking coating that are utilized in the invention (see paragraphs 20-21 and 35). One texture masking coating is taught to contain ethanol and water as the solvent at 90%, hydroxypropyl methylcellulose, polyethylene glycol 8000, and acesulfame potassium (see table B). The hydroxypropyl methylcellulose is taught to be about 6 cps when in a 2% solution (see paragraph 47). This coating is also taught to cover the entire surface of the core (see claim 64 and paragraph 32). Parikh et al. go on to teach that the optional ingredients that are taught for the taste masking coating are envisioned in the texture masking coating at the same amounts. The taste masking coating is taught to include surfactant at 2 wt% to 10 wt% where glycerol monostearate is particularly envisioned (see paragraph 41; instant claims 1-2). Since uniform coating would also be desired to mask unsavory texture in a drug particle, it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the texture-masking composition discussed with the foam technique of Lopez et al. with the added details of Hardie-Muncy et al. This modified reference does not specify the molecular weight of hydroxypropyl methylcellulose that corresponds to the taught viscosity.

Edgren et al. provide teachings regarding the molecular weight that corresponds to hydroxypropyl methylcellulose solution viscosities used in coatings for pharmaceutical dosage forms. In particular they teach that hydroxypropyl methylcellulose solution at 2% has a viscosity of about 3 cps has a molecular weight of about 9000 daltons (see paragraph 109). Since weight average molecular weight is the type of polymer molecular weight more commonly used in discussions of industrial uses of polymers, this value is interpreted to be a weight average molecular weight. As a known option for pharmaceutical coatings within the technical grasp of one of ordinary skill in the art, it would have been obvious to this ordinarily skilled artisan to use a hydroxypropyl methylcellulose with a weight average molecular weight of less than 9000. The result would be a composition where all the polymers had a weight average molecular weight of less than 9000. Therefore claims 1, 5, and 13 are obvious over Parikh et al. in view of McTeigue et al., Lopez, Hardie-Muncy et al., and Edgren et al. and as evidenced by the Merck Index and the USP Dictionary of U.S. Adopted Names and International Drug Names.

Response to Arguments

It is noted that applicant has indicated their willingness to file a terminal disclaimer should the instant claims become allowable.

Applicant's arguments filed February 23, 2009 have been fully considered but they are not persuasive. Also of note are the arguments presented regarding Davies et al. which was not relied upon in the rejections. Applicant argues that the coating compositions of McTeigue et al. are excluded by the recitation of the instant claims. Although applicant highlights an embodiment of the coating composition of McTeigue et al. that is outside the claimed ranges, McTeigue et al. also teach other compositions, as highlighted in the Office action, that do meet the proportion requirements of the instant claims (see example 2). The remaining arguments are moot in view of the new grounds of rejection.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615